

Listing of Claims:

76. (Previously Presented) A solid pharmaceutical composition for oral use comprising desglymidodrine or a pharmaceutically acceptable salt thereof together with one or more pharmaceutically acceptable excipients.
77. (Previously Presented) The composition according to claim 76, wherein desglymidodrine is selected from the group consisting of ( $\pm$ )- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol ( $\pm$  ST 1059), (+)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (+ ST 1059), (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059), and mixtures thereof.
78. (Previously Presented) The composition according to claim 77, wherein desglymidodrine is (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059).
79. (Previously Presented) The composition according to claim 76, wherein at least 90% w/w of desglymidodrine is (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059).
80. (Previously Presented) The composition according to claim 76, wherein desglymidodrine is present in the form of a pharmaceutically acceptable salt selected from the group consisting of a salt formed between desglymidodrine and an inorganic acid and a salt formed between desglymidodrine and an organic acid.
81. (Previously Presented) The composition according to claim 76 for buccal use.
82. (Previously Presented) The composition according to claim 76, wherein the

composition is selected from the group consisting of tablets, pellets, powders, granules, and particulate material.

83. (Previously Presented) The composition according to claim 76, in unit dosage form selected from the group consisting of a multiple unit dosage form and a single unit dosage form.
85. (Previously Presented) The composition according to claim 83, wherein the unit dosage form comprises a daily dose.
86. (Previously Presented) The composition according to claim 76, comprising an additional active drug substance.
87. (Previously Presented) The composition according to claim 86, wherein the additional active drug substance is midodrine or a pharmaceutically acceptable salt thereof.
88. (Previously Presented) The composition according to claim 87, wherein midodrine is selected from the group consisting of ( $\pm$ )-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide, (+)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide, (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide and mixtures thereof.
89. (Previously Presented) The composition according to claim 87, wherein midodrine is (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide.
90. (Previously Presented) The composition according to claim 89, wherein at least

90% w/w of midodrine is (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide.

91. (Previously Presented) The composition according to claim 82, wherein the composition is in the form of tablets having a disintegration time of at the most about 2.5 min.
92. (Previously Presented) The composition according to claim 76, wherein the composition has a shelf life at room temperature of at least 6 months.
93. (Previously Presented) The composition according to claim 76, wherein desglymidodrine is released from the composition with release kinetics corresponding to that of a plain release tablet.
94. (Previously Presented) A composition according to claim 93, wherein the release kinetics of desglymidodrine from the composition is selected from the group consisting of a zero order, a first order release, a mixture of zero and first order release, a 1½ order, a second order, a third order and a fourth order release.
95. (Previously Presented) A composition according to claim 93, wherein the composition is adapted to release desglymidodrine in such a manner that a relatively fast therapeutic effective concentration of desglymidodrine is obtained after administration of the composition.
96. (Previously Presented) The composition according to claim 95, wherein the composition is adapted to release desglymidodrine to obtain an onset of action of at the most 15 minutes after administration.

97. (Previously Presented) The composition according to claim 95, wherein the therapeutically effective concentration is obtained within 90 minutes from administration of the composition.
98. (Previously Presented) The composition according to claim 95, wherein a peak plasma concentration of desglymidodrine is obtained about 1 min to 6 hours after administration.
99. (Previously Presented) The composition according to claim 76, wherein the composition is a controlled release composition.
100. (Previously Presented) The composition according to claim 99, wherein the composition provides desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 2 hours after administration after administration.
101. (Previously Presented) The composition according to claim 99, wherein the composition is adapted to release desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for about 4.5-14 hours.
102. (Previously Presented) The composition according to claim 101, wherein the plasma concentration of desglymidodrine from the controlled release composition is maintained at a relatively constant level for about 4.5-14 hours.
103. (Previously Presented) The composition according to claim 102, wherein the relatively constant level  $n$  is  $\pm 60\%$ , and wherein  $n$  is the plasma concentration in ng/ml and is monitored in healthy persons.

104. (Currently Amended) The composition according to claim 99, wherein the release pattern of desglymidodrine from the controlled release composition when tested *in vitro* using a dissolution assay comprises:

release of 1-15% w/w from the composition within the first 30 minutes after the start of the assay;

release of 10-35% (~~25%~~) w/w about 30 minutes after the start of the assay;

release of 15-40% (~~35%~~) w/w about 1 hour after the start of the assay;

release of 20-50% (~~39%~~) w/w about 2 hours after the start of the assay;

release of 20-55% (~~47%~~) w/w about 3 hours after the start of the assay;

release of 25-75% (~~53%~~) w/w about 4 hours after the start of the assay;

release of 30-74% (~~66%~~) w/w about 6 hours after the start of the assay;

release of 40-95% w/w (~~80%~~) about 8 hours after the start of the assay;

release of 65-100% (~~93%~~) w/w about 10 hours after the start of the assay; and

release of 75-110% (~~100%~~) w/w about 12 hours after the start of the assay.

105. (Previously Presented) The composition according to claim 104, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate of midodrine is substantially the same as the release rates of desglymidodrine.

106. (Previously Presented) The composition according to claim 104, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate from the composition of the sum of midodrine and desglymidodrine calculated on a molar basis is substantially the same as the release rate for desglymidodrine.

107. (Previously Presented) The composition according to claim 99, wherein the controlled release composition comprises at least two parts such as at least a first and a second part, each part contains desglymidodrine and the first part being adapted to release desglymidodrine in a controlled manner during the first 0-14 hours after oral intake and the second part being adapted to release desglymidodrine, starting at least 6 hours after oral intake.
108. (Previously Presented) The composition according to claim 107, wherein at least one of the at least two parts is present in the composition in the form of a multiplicity of individual units.
109. (Previously Presented) The composition according to claim 107, wherein the two parts of the at least two parts are present in the composition in the form of a multiplicity of individual units and the two parts are in admixture.
110. (Previously Presented) The composition according to claim 108 or 109, wherein the individual units comprise pellets or minitablets.
111. (Previously Presented) The composition according to claim 107, wherein at least one of the at least two parts comprises at least two different types of pellets, , the first type of pellets corresponding to the first part and the second type of pellets corresponding to the second part.
112. (Previously Presented) The composition according to claim 107, wherein the composition is in the form of a multiple unit dosage form comprising at least two different types of minitablets, the first type of minitablets corresponding to the first part and the second type of minitablets corresponding to the second part.

113. (Previously Presented) The composition according to claim 107, further comprising a third part adapted to release desglymidodrine relatively quickly from the composition.
114. (Previously Presented) The composition according to claim 107, further comprising a fourth part adapted to release desglymidodrine from the composition 6-10 hours after administration.
115. (Previously Presented) The composition according to claim 107, further comprising a fourth part adapted to release desglymidodrine from the composition in the colon after oral intake.
116. (Previously Presented) A pharmaceutical kit comprising a composition comprising midodrine and a composition comprising a solid oral dosage form of desglymidodrine.
117. (Previously Presented) The kit according to claim 116, wherein either or both compositions is a controlled release composition.
118. (Previously Presented) A kit, comprising:
  - a fast onset solid oral dosage form of desglymidodrine formulated to provide a therapeutically effective concentration of desglymidodrine relatively quickly after administration, and
  - a controlled release pharmaceutical composition formulated to release desglymidodrine in a manner such that a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 2 hours.
119. (Previously Presented) The kit according to claim 118, wherein the fast onset solid

oral dosage form results in a peak or shoulder plasma concentration within 90 minutes upon administration.

120. (Previously Presented) The kit according to claim 118, wherein the fast onset composition is in the form of a tablet which is a melt tablet or sublingual tablet.
121. (Previously Presented) The kit according to claim 118, wherein the relatively fast onset composition is a buccal composition.
122. (Previously Presented) The kit according to claim 118, wherein the fast onset solid oral dosage form comprises desglymidodrine in an amount of from 0.2 mg to 10 mg.
123. (Previously Presented) A pharmaceutical kit comprising
  - a fast onset pharmaceutical composition comprising midodrine, formulated to provide a therapeutically effective concentration of midodrine relatively quickly after administration, and
  - a controlled release pharmaceutical composition formulated to release desglymidodrine in a manner such that a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 2 hours.
124. (Previously Presented) A pharmaceutical kit comprising
  - a fast onset fast onset solid oral dosage form formulated to provide a therapeutically effective concentration of desglymidodrine relatively quickly after administration, and
  - a controlled release pharmaceutical composition formulated to release midodrine in a manner such that a therapeutically effective plasma concentration of midodrine is maintained for at least about 2 hours.



125. (Currently Amended) A method for treating a condition ~~patient suffering from conditions~~ selected from the group consisting of orthostatic hypotension, syncope, urinary incontinence and urinary stress incontinence in a patient suffering there from, the method comprising orally administering the composition according to claim 76 to a patient in need thereof.
126. (Previously Presented) The method according to claim 125, wherein an administration of the composition takes place at wake-up time.
127. (Previously Presented) The method according to claim 125, wherein an administration of the composition takes place in the morning.
128. (Previously Presented) The method according to claim 125, wherein an administration of the composition takes place at in the middle of the day and is in the form of 1-2 tablets.
129. (Previously Presented) The method according to claim 125, wherein the administration takes place 1-3 times daily.
130. (Previously Presented) The method according to claim 125, wherein the administration takes place 1-2 times daily.
131. (Previously Presented) The method according to claim 125, wherein the administration takes place once daily.
132. (Previously Presented) A method according to claim 125, wherein a relatively fast onset composition comprising desglymidodrine is administered 1- 6 times daily.

133. (Currently Amended) A method for treating ~~a patient suffering from~~ a condition selected from the group consisting of septic shock and other conditions responsive to  $\alpha_1$  receptor stimulation in a patient suffering there from, the method comprising orally administering the composition of claim 76, to a patient in need thereof.
134. (Previously Presented) The method according to claim 125 or 133, wherein desglymidodrine is selected from the group consisting of ( $\pm$ )- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol ( $\pm$  ST 1059), (+)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (+ ST 1059), (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059), and mixtures thereof.
135. (Previously Presented) The method according to claim 134, wherein desglymidodrine comprises (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059).
136. (Previously Presented) The method according to claim 135, wherein at least 90% w/w of desglymidodrine is (-)- $\alpha$ -(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059).
137. (Previously Presented) The method according to claim 125 or 133, wherein desglymidodrine is present in the form of a pharmaceutically acceptable salt selected from the group consisting of a salt formed between desglymidodrine and an inorganic acid and a salt formed between desglymidodrine and an organic acid.
138. (Previously Presented) The method according to claim 125 or 133, wherein the composition is selected from the group consisting of tablets, pellets, powders, granules, and particulate material.

139. (Previously Presented) The method according to claim 125 or 133, wherein the composition is in a unit dosage form selected from the group consisting of a multiple unit dosage form and a single unit dosage form.
140. (Previously Presented) The method according to claim 139, wherein the unit dosage form comprises a daily dose.
141. (Previously Presented) The method according to claim 125 or 133, wherein the composition comprises a additional active drug substance.
142. (Previously Presented) The method according to claim 141, wherein the additional active drug substance is midodrine or a pharmaceutically acceptable salt thereof.
143. (Previously Presented) The method according to claim 142, wherein midodrine is selected from the group consisting of ( $\pm$ )-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide, (+)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide, (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide and mixtures thereof.
144. (Previously Presented) The method according to claim 143, wherein midodrine comprises (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide.
145. (Previously Presented) The method according to claim 144, wherein at least 90% w/w of midodrine comprises (-)-2-amino-N-( $\beta$ -hydroxy-2,5-dimethoxyphenethyl)acetamide.

146. (Previously Presented) The method according to claim 81, wherein the composition is in the form of tablets having a disintegration time of at the most about 2.5 min.
147. (Previously Presented) The method according to claim 125 or 133, wherein the composition has a shelf-life at room temperature of at least 6 months.
148. (Previously Presented) The method according to claim 125 or 133, wherein desglymidodrine is released from the composition with release kinetics corresponding to that of a plain release tablet.
149. (Previously Presented) The method according to claim 148, wherein the release kinetics of desglymidodrine from the composition is selected from the group consisting of a zero order, a first order release, a mixture of zero and first order release, a 1½ order, a second order, a third order and a fourth order release.
150. (Previously Presented) The method according to claim 149, wherein the composition is adapted to release desglymidodrine in such a manner that a relatively fast therapeutic effective concentration of desglymidodrine is obtained after administration of the composition.
151. (Previously Presented) The method according to claim 150, wherein the composition is adapted to release desglymidodrine relatively fast in order to obtain an onset of action at the most 15 minutes after administration.
152. (Previously Presented) The method according to claim 150, wherein the therapeutically effective concentration is obtained within 90 minutes from administration

of the composition.

153. (Previously Presented) The method according to claim 150, wherein a relatively fast peak plasma concentration of desglymidodrine is obtained within about 1 minute- 6 hours after administration.
154. (Previously Presented) The method according to claim 125 or 133, wherein the composition is a controlled release composition.
155. (Previously Presented) The method according to claim 125 or 133, wherein the composition is adapted to provide desglymidodrine in a manner such that a therapeutically effective concentration of desglymidodrine is maintained for at least about 2 hours after administration.
156. (Previously Presented) The method according to claim 154, wherein the composition is adapted to release desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for about 4.5-14 hours.
157. (Previously Presented) The method according to claim 156, wherein the plasma concentration of desglymidodrine from the controlled release composition is maintained at a relatively constant level for about 4.5-14 hours.
158. (Previously Presented) The method according to claim 157, wherein the relatively constant level  $n$  is  $\pm 60\%$ , and wherein  $n$  is the plasma concentration in ng/ml and is monitored in healthy persons.
159. (Currently Amended) The method according to claim 154, wherein the release pattern of

desglymidodrine in the controlled release composition when tested *in vitro* using a dissolution assay comprises:

release of 1-15% w/w from the composition within the first 30 minutes after the start of the assay;

release of 10-35% (~~25%~~) w/w about 30 minutes after the start of the assay;

release of 15-40% (~~35%~~) w/w about 1 hour after the start of the assay;

release of 20-50% (~~39%~~) w/w about 2 hours after the start of the assay;

release of 20-55% (~~47%~~) w/w about 3 hours after the start of the assay;

release of 25-75% (~~53%~~) w/w about 4 hours after the start of the assay;

release of 30-74% (~~66%~~) w/w about 6 hours after the start of the assay;

release of 40-95% w/w (~~80%~~) about 8 hours after the start of the assay;

release of 65-100% (~~93%~~) w/w about 10 hours after the start of the assay; and

release of 75-110% (~~100%~~) w/w about 12 hours after the start of the assay.

160. (Previously Presented) The method according to claim 159, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate of midodrine from the controlled release composition is substantially the same as the release rate of desglymidodrine.
161. (Previously Presented) The method according to claim 159, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate from the controlled release composition of the sum of midodrine and desglymidodrine calculated on a molar basis is substantially the same as the release rate for desglymidodrine.
162. (Previously Presented) The method according to claim 154, wherein the controlled release composition comprises at least a first and a second part, wherein each part

contains desglymidodrine and wherein the first part releases desglymidodrine in a controlled manner during the first 0-14 hours after oral intake and the second part releases desglymidodrine, starting at least 6 hours after oral intake.

163. (Previously Presented) The method according to claim 162, wherein at least one of the parts is present in the composition in the form of a multiplicity of individual units.
164. (Previously Presented) The method according to claim 163, wherein the individual units comprise pellets or minitabets.
165. (Previously Presented) The method according to claim 162, wherein the parts are in admixture.
166. (Previously Presented) The method according to claim 162, wherein at least one of the parts comprises at least two different types of pellets.
167. (Previously Presented) The method according to claim 162, wherein the first part comprises a first type of pellet and the second part comprises a second, different type of pellet.
168. (Previously Presented) The method according to claim 162, wherein the first part comprises a first type of minitabets and the second part comprises a second, different type of minitabets.
169. (Previously Presented) The method according to claim 162, wherein the composition further comprises a third part adapted to release desglymidodrine relatively quickly from the composition.

170. (Previously Presented) The method according to claim 169, wherein the composition further comprises a fourth part adapted to release desglymidodrine from the composition 6-10 hours after administration.
171. (Previously Presented) The method according to claim 169, wherein the composition further comprises a fourth part adapted to release desglymidodrine from the composition in the colon after oral intake.